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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,940	01/21/2004	Gyorgy Domany	1000546-0003	4047

7590 12/26/2006  
Matthew O Brady  
RAKOCZY MOLINO MAZZOCHI LLP  
Suite 500  
6 West Hubbard Street  
Chicago, IL 60610

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/26/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/761,940	DOMANY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 5,9,12 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4,6-8,10,11,13,14 and 16-37 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                       |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. Applicant's election without traverse of group I, claim 15, with the species 2-[4-(4-fluoro-benzyl)-piperidin-1-yl]-2-oxo-N-(2-oxo-2,3-dihydro-benzoxazol-6-yl)-acetamide in the reply filed on Sept. 27, 2006 is acknowledged.

Based on the election, claim 15 and claims 1-4, 6-8, 10-11, 13-14, 16-37 reading on claim 15, wherein U-V forms a ring are prosecuted. Claims 5, 9, 12, 38 and the remaining subject matter of claims 1-4, 16-37 are withdrawn from consideration per 37 CFR 1.142(b).

Based on the election of claim 15, the subject matter wherein U-V forms a ring is examined while the subject matter being drawn to U and V are independent substituents will be restricted for the following reason. It has been documented that the core containing piperidine with U and V being independent substituents do not share the same utility as those wherein U-V are ring as the elected compounds. It is evidenced that the U and V are independent substituents compounds are neuropeptide Y5 ligands (see CA 142:240321).

The restriction is proper especially, it has been clearly found by the PCT search result that very large number of documents relevant to the issue of novelty were found initially, thus, only limited meaningful search was conducted.

2. Claims 1-4, 6-7, 10, 13, 16-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein U-V forms ring as disclosed on page 5, lines 7-10, does not reasonably provide enablement for the unlimited scope of all heterocyclic rings encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This is a scope of enablement rejection. Without description and specific provision of the starting material for such structure, the specification provided insufficient description as well as starting material sources for the breadth of the scope. Starting material at the point of novelty is particularly pertinent in chemical compounds since absent of starting material sources, the public is offered mere language rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarth 210 USPQ 289.

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3. Claims 1-4, 6-8, 10-11, 13-14, 16-28 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2<sup>nd</sup> 1400 (1988) decision.

The analysis is applied to the instant case.

#### Nature of invention

The claims are drawn to compounds and their composition for the use of treating pathologies requires antagonism of NMDA receptor.

#### The state of the art and predictability

Receptor binding requires very specific structural conformation of a given compound (see Silverman p.72-76). Especially in NMDA receptor binding field, it is well recognized in the art that potent NMDA receptor antagonists of similar chemical structure have severe side effects, thus, makes such compounds unable to be useful as drugs (see CA 145:158900).

Further, there are many subtypes of NMDA receptors and each subtype has independent and distinct physiological function for which a single compound does not operate multiple sites (see CA 141:47098).

#### The amount of guidance and working examples

The specification disclosed on pages 14-19 that examples of the prepared compounds have compatible activity as the known NMDA antagonists Ro 25-6981. Thus, the compounds

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have limited nexus based on the compatibility with Ro 25-6981 for operability of the conventionally known pathology for Ro 25-6981 i.e. ischemic damage of the brain (see CA 142:232125, Richter) for compounds of claim 15. The specification together with the complexity of the field provided no description or enablement for the compounds to be operable for *all* NMDA receptor antagonistic activity including those have not yet been discovered at the time the invention was made.

4. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

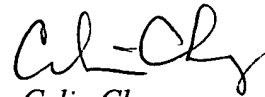
The closest prior art (UD 6,399,631, col. 69, compound 69) differ from the instant claim 15 in that the U-V fused ring system was further fused with an additional benzene and X is an isostere instead of carbonyl. Therefore, compounds of claim 15 limited to the particularly disclosed bicyclic ring system of claim 14 are neither anticipated nor rendered obvious by the art of record.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Dec. 20, 2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625